

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	) ) ) ) _____)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	) ) )	2:16 MD 1203

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

August 28, 2007

Paul Jones ("Mr. Jones" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Rosemary Jones, Mr. Jones' spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In June 2002, claimant submitted a completed Green Form to the Trust signed by his attesting physician Carrie A. Totta, M.D. Based on an echocardiogram dated March 22, 2002, Dr. Totta attested in Part II of claimant's Green Form that he suffered from moderate mitral regurgitation and an abnormal left atrial dimension.<sup>4</sup> Additionally, Dr. Totta attested that claimant had

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contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Totta also attested that Mr. Jones had mild aortic regurgitation. As Mr. Jones' claim does not present any of the conditions necessary to receive Matrix Benefits for damage to his aortic valve, his level of aortic regurgitation is not relevant  
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mitral valve prolapse, which is a reduction factor that requires the payment of benefits on Matrix B-1.<sup>5</sup> Based on such findings, claimant would be entitled to Matrix B-1, Level II benefits in the amount of \$93,507.

In the report of claimant's echocardiogram, Dr. Totta stated that claimant had moderate mitral regurgitation with a Regurgitant Jet Area ("RJA") to Left Atrial Area ("LAA") ratio of 22%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Dr. Totta also stated that claimant's left atrium "is moderately dilated measuring 6.5 cm in the apical view." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id.

§ IV.B.2.c.(2) (b) .

In June 2003, the Trust forwarded the claim for review by Michael A. Rihner, M.D., one of its auditing cardiologists. In audit, Dr. Rihner concluded that there was no reasonable

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4 (...continued)  
to this claim. See Settlement Agreement § IV.B.2.c.(2) (a) .

5. The Trust's auditing cardiologist found that claimant did not have mitral valve prolapse. The attesting physician, however, concluded that claimant had this condition and this finding was confirmed by the Technical Advisor. Accordingly, we find that this claim should be paid in accordance with Matrix B-1.

medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because his echocardiogram demonstrated only mild mitral regurgitation. In particular, Dr. Rihner observed that the "[mitral regurgitant] jet area was overestimated by the sonographer." Dr. Rihner also concluded that there was no reasonable medical basis for Dr. Totta's finding of an enlarged left atrial dimension because, by his measurements, the claimant's "LA is normal in size."<sup>6</sup>

Based on Dr. Rihner's diagnoses of mild mitral regurgitation and a normal left atrial dimension, the Trust issued a post-audit determination denying Mr. Jones' claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>7</sup> In contest, claimant submitted two supplemental expert reports by Jeffrey S. Fierstein, M.D., F.A.C.C., dated September 11, 2003, and Emeke Nkadi, M.D., dated September 8, 2003.<sup>8</sup> In their

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6. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b).

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Jones' claim.

8. Claimant also submitted an April 17, 2003 echocardiogram  
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supplemental reports, Drs. Fierstein and Nkadi concurred with the attesting physician's finding of moderate mitral regurgitation and an abnormal left atrial dimension. In particular, Dr. Fierstein stated that claimant had an RJA/LAA ratio of 24% and that his left atrial dimension measured 5.5 cm in the apical four-chamber view. Dr. Fierstein further stated, in pertinent part, that:

With regard to these areas of dispute, I have concluded that the attesting physician did have a reasonable medical basis for reaching the conclusion that the degree of mitral regurgitation is >20% with multiple jets recorded in the apical 4,3 and 2 chamber views which satisfy this criterion.

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Mitral Regurgitation is demonstrated, for example, in loop Nos. 90, 131, and 135. My calculations of MR are based on loop No. 131, which shows the RJA, and Loop No. 129, which shows the Left Atrial Area. Loop No. 129 shows the A4 measurement of the LA, while Loop No. 19 shows the PLAX measurement of the LA.

In the second supplemental report, Dr. Nkadi stated that claimant had an RJA/LAA ratio of 21%. Dr. Nkadi also explained that:

Mitral Regurgitation is demonstrated, for example, in loop Nos. 95 through 100. My calculations of MR are based on loop No. 134, which shows the RJA, and Loop No. 128, which

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report by Omar Nass, M.D., for an unidentified individual, in which Dr. Nass stated that "[m]itral regurgitation appears mild by visual estimation; however, by area planimetry it is up to moderate." Claimant argued that this report confirmed that "'eyeballing' is not accurate."

shows the Left Atrial Area. Loop No. 128 shows the A4 measurement of the LA, while Loop No. 19 shows the PLAX measurement of the LA.

Claimant argued that the reports of Drs. Fierstein and Nkadi provided a reasonable medical basis for his claim.

Claimant also argued that the auditing cardiologist: (1) "failed to accurately measure the area of mitral regurgitation, left atrial area, and left atrial diameter"; (2) "failed to apply the appropriate standard of 'reasonable medical basis'"; and (3) "substituted his judgment for that of the attesting physician." Finally, claimant argued that the auditing cardiologist "eyeballed" his level of regurgitation as opposed to taking actual measurements.

The Trust then issued a final post-audit determination, again denying Mr. Jones' claim. With its determination, the Trust included another declaration prepared by the auditing cardiologist, Dr. Rihner, who was asked to review Mr. Jones' claim for a second time. In his declaration, Dr. Rihner concluded that claimant had only mild mitral regurgitation. Dr. Rihner stated that the frames relied upon by Drs. Fierstein and Nkadi were overtraced and did not depict mitral regurgitation. Dr. Rihner further stated that:

[T]he vast majority of frames show mild mitral regurgitation. Furthermore, the frames relied upon by Claimant's Attesting Cardiologist and expert improperly increased the percentage of mitral regurgitation, overestimating the RJA by overtracing the jets to include non-regurgitant flow in the measurement of the RJA.

Dr. Rihner also reiterated his findings that claimant had a normal left atrial dimension stating that:

In addition, I again concluded that Claimant's left atrial dimensions are normal and specifically that the Claimant's left atrium measures less than 5.3 cm in the apical four chamber view.

Claimant disputed the Trust's final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807 (Mar. 26, 2003), Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Jones' claim should be paid. On January 14, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3217 (Jan. 14, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on March 26, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>9</sup> to review claims after the Trust and

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may use a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions." Id.

claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. Rule 35.\_\_\_\_\_

\_\_\_\_\_The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's findings that he had moderate mitral regurgitation and an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answers in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there was a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).\_\_\_\_\_

\_\_\_\_\_ In support of his claim, Mr. Jones reasserts the arguments he made in contest. Claimant also argues, among other things, that: (1) the auditing cardiologist only "eyeballed" his level of regurgitation and, therefore, his opinions are subjective and unreliable; (2) the auditing cardiologist did not measure the maximum regurgitant jet, as required by the

Settlement Agreement; (3) the auditing cardiologist conceded that he observed moderate mitral regurgitant jets by concluding that a vast majority of frames showed mild mitral regurgitation; and (4) inter-reader variability accounts for the difference in opinions between the auditing cardiologist and the attesting physician.

In response, the Trust argues that the auditing cardiologist concluded that the frames planimetered by the attesting physician were overtraced and were not representative of the level of claimant's regurgitation. The Trust further argues that: (1) the circumstances surrounding the preparation of claimant's Green Form are suspect because, in addition to completing this form, Dr. Totta signed 45 other Green Forms on the same date and had attested to more than 430 total Green Forms; (2) eyeballing the regurgitant jet is well accepted in the world of cardiology; (3) the auditing cardiologist properly applied the "reasonable medical basis standard" and that claimant's arguments are contrary to the interpretation of the Settlement Agreement; and (4) the supplemental expert opinions of Drs. Fierstein and Nkadi do not establish a reasonable medical basis for the attesting physician's representation because they relied on frames that do not depict mitral regurgitation and improperly increased the percentage of mitral regurgitation.<sup>10</sup>

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10. In its show cause submissions, the Trust argues that, under Rule 26(a)(2) of the Federal Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously  
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The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Vigilante stated that:

There was a turbulent and high velocity jet of mitral regurgitation that was very eccentric and traveling anteriorly into the left atrium. This abnormal jet coincided with the presence of posterior mitral valve prolapse. Although the still frame images of loops 131 and 134 were not representative of the true severity of mitral regurgitation, I was able to accurately determine the RJA on multiple other loops in the apical four chamber view. The LAA was accurately determined on loops 128 and 129. I planimetered multiple regurgitant jet areas and several left atrial areas. The RJA/LAA ratio was between 22 and 26%. This ratio qualified for moderate mitral regurgitation.

Dr. Vigilante also found that there was a reasonable medical basis for the attesting physician's finding of an abnormal left atrial dimension. As explained by Dr. Vigilante:

Multiple loops were present on this tape and these were all reviewed. The left atrium was dilated in the supero-inferior systolic dimension. I made multiple measurements of this structure and determined that the left atrium measured 5.8 cm in the supero-inferior systolic dimension. This measurement occurred from the mitral annulus to the back of the left atrium. This measurement was able to be accurately determined on loops 128 and 129 of the study.

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stated that Rule 26(a)(2) disclosures are not required under the Audit Rules. See PTO No. 6996 (Feb. 26, 2007).

Finally, Dr. Vigilante found that claimant's echocardiogram demonstrated mitral valve prolapse.<sup>11</sup>

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for his claim. Claimant's attesting physician, Dr. Totta, reviewed claimant's echocardiogram and found that claimant had moderate mitral regurgitation and an abnormal left atrial dimension. Although the Trust contested the attesting physician's conclusion, Dr. Vigilante confirmed the attesting physician's findings. Specifically, Dr. Vigilante concluded that claimant's echocardiogram demonstrated "an eccentric jet of moderate mitral regurgitation into the anterior portion of the left atrium", an RJA/LAA ratio between 22% and 26% in the apical four chamber view. Dr. Vigilante further found that claimant's "left atrium measured 5.8 cm in the supero-inferior systolic dimension." Under these circumstances, claimant has met his burden in establishing a reasonable medical basis for his claim.<sup>12</sup>

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11. Under the Audit Rules, claimant and the Trust were afforded the opportunity to respond to the Technical Advisor's Report. See Audit Rule 34. The Trust submitted a response to the Technical Advisor Report in which the Trust asserted that Dr. Vigilante concluded that claimant had mitral valve prolapse and, therefore, "in the event that these findings are adopted, the presence of this reduction factor would require payment of this mitral valve Claim on Matrix B."

12. Accordingly, we need not address claimant's remaining arguments.

For the foregoing reasons, we conclude that claimant has met his burden of demonstrating that there is a reasonable medical basis for his claim and is consequently entitled to Matrix Benefits. As claimant has conceded that he has mitral valve prolapse, claimant is entitled to Matrix B-1, Level II benefits. Therefore, we will reverse the Trust's denial of the claims submitted by Mr. Jones and his spouse for Matrix Benefits.

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AMERICAN HOME PRODUCTS CORPORATION	) ) )	2:16 MD 1203

PRETRIAL ORDER NO.

AND NOW, on this 28th day of August, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that claimants Paul Jones, and his spouse, Rosemary Jones, are entitled to Matrix B, Level II benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805 and shall reimburse claimant for any Technical Advisor costs incurred in the Show Cause process.

BY THE COURT:

/s/ Harvey Bartle III

C. J.